Appln. No.: 10/629,308 Amendment Dated May 4, 2009 Reply to Office Action of August 19, 2008

<u>Amendments to the Claims:</u> This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

 (Currently Amended) A sterile aqueous pharmaceutical composition for parenteral administration of propofol, said composition comprising about 1% (w/v) propofol and less than 15% (w/v) excipients, said excipients comprising:

7% to 9% (w/v) poloxamer component consisting essentially of Poloxamer 188; 2% to 4% (w/v) polyethylene glycol; and less than 1% (w/v) lipid,

wherein the composition further comprises less than 5% (w/v) of total propofol degradants when maintained at $25^{\circ}C_7$ 40 °C₇ or 60 °C for 4 weeks, and the composition is clear to the naked eye.

2 - 5. (Canceled)

6. (Previously Presented) The composition of Claim 1, wherein said polyethylene glycol comprises polyethylene glycol 400, and wherein said excipients further comprise one or more compounds selected from the group consisting of citric acid, disodium edetate, metablsulfate, benzyl alcohol, propylene glycol, an antioxidant, a preservative, an antimicrobicidal.

7. (Canceled)

- 8. (Previously Presented) The composition of Claim 1, wherein:
- a) said composition has a particle size diameter of between 25 and 200 nm;
- b) said composition has a particle size diameter of between 50 and 100 nm; or
- c) said composition forms particles of similar particle size.
- 9. (Currently Amended) The composition of Claim 1, wherein:
- a) said composition does not support microbial growth; or
- b) said composition is microbicidal:-or

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e) said-composition is sufficient for no more than a 10-fold increase in growth, of Staphylococcus aureus ATCC 6538, Escherichia coli ATCC 8739, Pseudomonas aeruginosa ATCC 9027 or Candida albicans ATCC 10231 for at least 24 hours.

10. (Canceled)

- (Previously Presented) The composition of Claim 1, further comprising:
- a) an acid:
- b) a base;
- c) a local anesthetic:
- d) a second general anesthetic:
- e) an antimicrobial agent;
- f) a surfactant;
- g) a tonicity modifier;
- (i) wherein said tonicity modifier is glycerol;
- h) a pH modifier; or
- i) a second, third, fourth, fifth, or sixth excipient.
- 12. (Currently Amended) The composition of Claim 1, wherein said composition is substantially free comprises less than about 0.5% (w/v) of: a. an antimicrobial agent; or b. a preservative.
- 13,-24, (Canceled)
- 25. **(Currently Amended)** A sterile aqueous pharmaceutical composition for parenteral administration of propofol, said composition comprising about 1% (w/v) propofol and less than 15% (w/v) excipients, said excipients comprising:

7% to 9% (w/v) poloxamer component consisting essentially of Poloxamer 188;

2% to 4% (w/v) polyethylene glycol;

0% to 1% (w/v) propylene glycol; and

less than 1% (w/v) lipid, wherein the composition is clear to the naked eye.

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- 26. (Previously Presented) The composition of Claim 25, wherein said excipients comprise: 8% (w/v) Poloxamer 188; 3% (w/v) polyethylene glycol 400; and 1% (w/v) propylene glycol.
- 27. (Previously Presented) The composition of Claim 1, wherein said composition is stored in a container having a means for dispensing the composition.
- 28. (New) The composition of claim 1, wherein said excipients include citric acid or a salt thereof.
- 29. (New) The composition of claim 28, wherein said citric acid is present in an amount of about 0.1 to about 2% (w/v).